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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,151	05/18/2006	George C. Prendergast	3882-P03161US2	4302

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DANN, DORFMAN, HERRELL & SKILLMAN
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SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

STONE, CHRISTOPHER R

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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04/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,151	Applicant(s) PRENDERGAST ET AL.	
	Examiner CHRISTOPHER R. STONE	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-37, 40 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 41-47 and 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 15, 2009 has been entered.

Applicants' arguments, filed January 15, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-56 are pending. Claims 1-37, 40, 48-52 are withdrawn from consideration. Claims 38, 39, 41-47 and 53-56 are under examination. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38, 39, 41-47 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munn et al (US PGPUB 2001/0001040) in view of Hausheer et al (US 5,902,610)

Claims 38, 39, 41-47 and 54-56 are drawn to a method of treating cancer comprising administering an IDO inhibitor and a chemotherapeutic agent. Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT) and cisplatin are the elected species of IDO inhibitors and chemotherapeutic compound currently under examination.

Munn et al teaches that IDO inhibitors, including 1MT, are useful in the treatment of cancer (paragraph [0017]). Munn et al does not teach the administration of cisplatin with 1MT. Hausheer et al teaches that cisplatin is a widely used anticancer agent used in combination with other anticancer agents in the treatment of a broad spectrum of cancers, including e.g. breast, lung, head and neck, ovary, etc. (column 3, lines 32-39). Hausheer et al further teaches that additional anticancer agents can be administered

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prior to, simultaneously or following the administration of cisplatin in combination therapies (column 1, lines 11-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to administer 1MT and cisplatin, concurrently or sequentially, in any order, to treat cancers, including breast, lung, head and neck, ovary, etc., since both compounds were known to be useful chemotherapeutic agents, thus resulting in the instantly claimed invention with a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38, 39, 41-47 and 53-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 and 28-34 of copending Application No. 10550444. Although the conflicting claims are

not identical, they are not patentably distinct from each other because claims 27 and 28-34 of copending Application No. 10550444 are drawn to a method of treating cancers, including breast cancer comprising administering an IDO inhibitor of formula I and a anticancer agent, including cisplatin, concurrently or sequentially, in any order. Formula I is defined in the disclosure of Application No. 10550444 (figures 26 and 27) to include the instantly claimed compounds, Methyl-TH-DL-Trp, 1-methyl-DL-tryptophan (1MT).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the rejection of claims 38, 39, 41-47, 53 and 54 under 35 U.S.C. 112, first paragraph, have been considered but are moot in view of the new ground(s) of rejection. In view of the findings of fact in the art as noted above that indicates that cisplatin and 1MT are known to be useful and enabled for the treatment of a broad spectrum of cancers and upon further consideration and in light of the art cited above teaching that cisplatin and 1MT alone are useful as antiproliferative agents, it does not appear that the instantly examined combination of cisplatin and 1MT, results in any unexpected result, i.e. synergy. Example 4 (figure 11) of the instant application and the declaration, filed July 7, 2008 display merely additive results in percent inhibition relative to the untreated control. The additive inhibition results in a reduction in breast tumor volume as expected and is not synergistic which by definition is a greater than additive result. In submitting evidence asserted to establish unobvious results, applicant has a burden of indicating how the examples representing the claimed invention relate to the prior art examples and how the latter represent the closest prior art, submitting evidence reasonably commensurate in scope with the claimed subject matter, establishing that the differences are in fact unexpected and unobvious and of statistical and practical significance. Ex parte Gelles, 22 USPQ2d 1318 (BPAI 1992). Further, a showing of unobviousness must be commensurate in scope with the claims

which the evidence is offered to support. To warrant the allowance of generic claims, the showing of unobviousness must include enough examples to be reasonably representative of the genus. Although objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support, the probative value of a narrow range of data can be reasonably extended to prove the unobviousness of a broader claimed range when one could ascertain a trend in the exemplified data which would allow him to reasonably extend the probative values thereof. In re Clemens et al. 206 USPQ 289 (CCPA 1980). In re Kollman et al. 201 USPQ 193 (CCPA 1979).

For instance, in the instant case with regard to alleged unexpected synergy, Applicant would have to provide data or other evidence that a synergistic result would be reasonably expected to be observed across physiologically and etiologically distinct cancer species encompassed by the genus cancer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

26March2008

CRS

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645